

REMARKS

Applicants appreciate the statement by the Office that the previous amendments to claims 1 and 34, responsive to the claim objection and the §112, second paragraph, rejection of the prior Office Action, have been withdrawn.

The Rejections:

In the present Office Action, claims 1-39 are rejected under Section 112, first paragraph, concerning the written description requirement, and claims 1-18 and 29-38 are newly rejected under Section 112, second paragraph, raising a specific indefiniteness matter.

Claims 1-39 are rejected under 35 U.S.C. §103 from Aoyama U.S. Patent No. 6,827,963 in view of Wester U.S. Patent No. 6,589,588 and St.-Onge et al. "Phytosterols and Human Lipid Metabolism: Efficacy, Safety and Novel Foods."

Claim Amendments and the Section 112 Rejections:

The present Amendment revises the single independent composition claim and single method-for-making independent claim 19. Each such claim is amended in direct response to the Section 112 rejections.

Regarding the Section 112, second paragraph, rejection, claim 1 is amended to remove "randomization" before "reacted". Claim 1 is further amended to recite that the structured lipid component is an interesterification product that is a "randomization product," and claim 19 is similarly amended.

Support is found, for example, in line 5 of paragraph [0012] of the specification as filed. It is respectfully believed that this revision obviates the Section 112, second paragraph, rejection. Reconsideration and withdrawal thereof are respectfully requested.

Regarding the Section 112, first paragraph, rejection, both of the independent claims are amended to remove the wording "first fatty acid chains and second fatty acid chains". Each independent claims now recites instead "one glycerol component with fatty acid moiety chains" and "another glycerol component with fatty acid moiety chains". Direct support is found, for example, at lines 5-8 of paragraph [0012].

With further reference to the Section 112, first paragraph, rejection, both independent claims are amended to recite that the interesterification product is a randomization "wherein fatty acid moiety chains from said one glycerol component are exchanged with fatty acid moiety chains from said another glycerol component, resulting in triglycerol structures which have interexchanged fatty acid moiety chains that vary randomly from glycerol structure to glycerol structure." Direct support therefor is found, for example, in lines 5 and 8-10 of paragraph [0012], paragraph [0020], the last sentence of paragraph [0035] and the combination of paragraphs [0055], [0087] and [0093].

It is respectfully believed that these revisions of claims 1 and 19 obviate the Section 112, first paragraph, rejection. Reconsideration and withdrawal thereof are respectfully requested.

In addition, both independent claims are amended to explicitly state that the reaction is carried out in the presence of an interesterification catalyst, which is fully supported by paragraph [0035]. Such interesterification catalysts are more specifically defined in paragraph [0036], from which it will be noted do not include enzymes.

**The Section 103 Rejections:**

As presently amended, claims 1 and 19 require a catalyst interesterified randomization product and method wherein fatty acid moiety chains from the C-6-12 glycerol component (MCTs) are exchanged with fatty acid moiety chains from the C-16 or greater glycerol component (long chain oil), this product being triglycerols that have interexchanged fatty acid moiety chains that vary randomly from glycerol structure to glycerol structure. All of the remaining claims are dependent upon either claim 1 or claim 19. This catalyst interesterified structured lipid is combined with a phytosterol ester component in the percentages specified in the claims.

Pages 4-5 and 8 of the Office Action refer to lines 11-23 in column 8 of Aoyama for the proposition of the Office that Aoyama "intrinsically" discloses triglycerides prepared by random interesterification where first and second fatty acid chains vary randomly from glycerol structure to glycerol structure. Applicants appreciate that lines 20-21 in column 8 of Aoyama recite the phrase "a chemical synthesis method." This is the one and only time Aoyama provides any disclosure or alleged teaching about "chemical synthesis." It is of course

very evident from Aoyama that any degree of Aoyama enablement or disclosure for ester preparation concerns only the enzyme method to prepare the Aoyama fats and oils composition. In addition to the phrase "a chemical synthesis method," this paragraph in column 8 of Aoyama also mentions "a method of extracting from natural fats and oils" as well as "a genetic recombination method of oil seeds." As with the "chemical synthesis" method, Aoyama provides no disclosure concerning these other two methods, other than to name them.

The secondary references to Wester and St.-Onge do not concern interesterification and accordingly the focus of the present paper concerns what one of ordinary skill in the art would have been taught by Aoyama without the benefit of applicants' disclosure and teaching. One of ordinary skill in the art would need more guidance than the mere statement of "chemical synthesis method," which is all that is provided by Aoyama. Aoyama does not enable one of ordinary skill in the art to make the compositions according to his invention by using the "chemical synthesis method." Of course, even if this were the case, the product and method of the present claims is not present in Aoyama. The only enablement provided in Aoyama is making the Aoyama fats and oils composition by the enzyme method.

More to the point of applicants' claimed invention, Aoyama does not disclose or teach the structured lipid component of claims 1 and 19. Instead, as noted previously, Aoyama teaches driving the esterification to triglycerides in which specified fatty acids are combined so as to provide a specific acyl group

at the first portion, a specific acyl group at the second portion and a specific acyl group at a third portion of the triglyceride molecule. Same are disclosed by Aoyama as Formulas, namely Formula I, Formula II, Formula II', Formula III, Formula III', Formula IV, Formula V or Formula VI. Thus, Aoyama teaches glycerol backbones having fatty acids placed thereon at a specific position on the glycerol backbone, which would not have obviously led one of ordinary skill in the art to applicants' claimed product and method discussed above.

On page 11 of the Office Action, in response to applicants' previous arguments, the phrase "a chemical synthesis method" in column 8 of Aoyama is relied upon for concluding:

Aoyama discloses a chemical  
interesterification method substantially  
similar to randomization described by  
applicant, that Aoyama discloses a  
triacylglycerol structure which has  
interchanged fatty acid moieties that vary  
from glycerol structure to glycerol  
structure.

Relying on the phrase "a chemical synthesis method" does not negate the fact that Aoyama does not disclose the interesterified randomization product or method specified in claims 1 and 19, either intrinsically or otherwise. Additionally, this one-time mention of "a chemical synthesis method" in column 8 of Aoyama would not have taught one of ordinary skill in the art to expect formation of applicants' product. Furthermore, Aoyama does not even remotely enable one of ordinary skill in the art to achieve applicants' claimed product and method.

In support of the unobviousness of applicants' invention as specified in claims 1 and 19 over Aoyama, applicants accompany the present paper with a Declaration of Karl A. Scheidt under Rule 132. The accompanying Scheidt Declaration successfully, applicants respectfully assert, rebuts the *prima facie* case proffered by the Office as permitted by M.P.E.P. §2145, which states:

A conclusion of obviousness requires that the reference(s) relied upon be **enabling in that it put the public in possession of the claimed invention.** (citing *In re Hoeksema*, 399 F.2d 269, 274, 158 USPQ 596, 601 (CCPA 1968), **bolding added.**)

\* \* \*

The *Hoeksema* court further noted that once a *prima facie* case of obviousness is made by the PTO through citation of references, the burden is on the applicant to produce contrary evidence establishing that the reference being relied on **would not enable a skilled artisan** to produce the different compounds claimed. *Id.* At 274-75, 158 USPQ at 601. See also *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F2d 281, 295, 297, 227 USPQ 657, 666, 667 (Fed. Cir. 1985) (citing *Hoeksema* for the proposition above); *In re Grose*, 592 F.2d 1161, 1168, 201 USPQ 57, 63-64 (CCPA 1979).

In his Declaration, Professor Scheidt fully supports applicants' position that Aoyama's teachings and disclosure regarding using the enzyme method to drive the esterification toward the Aoyama compositions that Aoyama identifies as triglycerides of specific structures, namely the Formulas noted

above, does not intrinsically result in or otherwise enable the interestified randomization product and method of current claims 1 and 19. Professor Scheidt also observes, for example, in paragraph 12, that Aoyama does not disclose an interesterified randomization structured lipid commensurate with the present claims.

Furthermore, Professor Scheidt, after considering the entirety of Aoyama, concludes that same is not even remotely adequate to prepare the invention of the present claims, namely a structured lipid that is an interesterified randomization product with fatty acid moiety chains from one glycerol exchanged with fatty acid moiety chains from another, different glycerol, such structured lipid having randomly interexchanged different fatty acid moiety chains that vary from glycerol structure to glycerol structure. Nor does Aoyama, Professor Scheidt observes, teach or enable the skilled esterification artisan about randomly interexchanged structured lipids or a method of making same, as presently claimed.

Basic points are made by Professor Scheidt in this regard. He questions if it is even possible to make the fats and oils composition described in Aoyama by "a chemical synthesis method," which Aoyama says is the case. Applicants observe thus that Aoyama's totally unsupported and gratuitous phrase "a chemical synthesis method" does not come close to rising to the level of enablement for Aoyama's Formulas fats and oils composition. This being the case, it is impossible for Aoyama to enable preparation of applicants' claimed product and method

since same are not at all the subject of Aoyama and they are not described by Aoyama, intrinsically or otherwise.

Professor Scheidt, for example in paragraph 13, states that Aoyama's use of the phrase "a chemical synthesis method" does not mean that applicants' structured lipids intrinsically are prepared by random interestification, even if Aoyama uses MCTs and long-chain lipids as the reactants. This is because enzymes and chemical catalysts are very different from each other and would require much more than the simple statement "a chemical synthesis method" in order to intrinsically teach or enable preparation of a different product by a different means.

Professor Scheidt points out that enzymes and chemical catalysts are very different from each other. Each reacts with substrates at different rates and with different selectivities based on many characteristics such as shape, size and electrostatic interactions. For example, enzymes are relatively complex large chemical structures, while chemical catalysts are of a relatively small and simple chemical structure. Professor Scheidt reports the skilled artisan would need details of interesterification conditions, such as whether the chemical synthesis conditions are under an acidic or a basic condition.

Applicants observe that, since Aoyama provides absolutely no information on chemical interestification conditions, what chemicals would be used in "a chemical synthesis method" or anything else about chemical synthesis, and since these types of details are essential, Aoyama would not enable a skilled artisan to produce the invention of current claims 1 and 19.



Professor Scheidt, in summary, reaches these conclusions:

- A. The skilled esterification artisan is not taught or enabled by Aoyama how to make the Aoyama Formula fats and oils composition by "a chemical synthesis method."
- B. The skilled esterification artisan would be taught by Aoyama that "a chemical synthesis method" would not drive interesterification to or toward randomization as presently claimed.
- C. The esterification artisan would not be enabled to achieve random interexchanging through interesterification by the simple statement in Aoyama of "a chemical synthesis method" inasmuch as Aoyama is devoid of absolutely essential conditions.

In the Office Action, Wester is relied upon to address Aoyama's failure to disclose phytosterol esters. Wester is cited as teaching incorporation of phytosterol esters into specific foods including cooking oils to reduce serum cholesterol in the body by reducing the absorption of cholesterol from the digestive tract. Because Wester has no teaching concerning random interesterification or the structured lipid components that are claimed by applicants and that are not taught or contemplated by Aoyama, Wester does not remove Aoyama's extensive deficiencies.

The St.-Onge reference is cited for its teaching of phytosterols dosing efficacious in lowering cholesterol. St.-Onge does not remove Aoyama's or Wester's deficiencies regarding

the claimed randomized interesterified structured lipids or the randomization interesterification that applicants claim.

In response to the statements in the Office Action on the rejection of claims 2-5, 30-33 and 37, applicants have shown Aoyama does not disclose or inherently teach an oil composition identical to that presently claimed. Accordingly, it cannot be concluded that "modified" Aoyama would display the health benefits recited in these claims.

Regarding claims 11-13, 20-21, 35-36 and 39, Aoyama does not disclose or inherently teach the triglycerides as now claimed and thus does not disclose intrinsically or otherwise the viscosity and smoke point properties of these claims.

Similar observations are made in response to the statements in the Office Action concerning claims 14-17 and 38.

Further concerning amended independent method claim 19, Aoyama does not disclose or inherently teach the random interesterification steps of this claim in the presence of an interesterification catalyst.

Concerning claims 22-29 and 34, these claims are not obviously arrived at since the dosing and risk-reduction features with the Formula fats and oils composition of Aoyama (even if used with Wester or St.-Onge) cannot be expected to be the same features of these claims, due to differences between the lipids of Aoyama and those of the present claims, including their method of preparation according to claim 19.

For these reasons, with the combination of references posited by the Office in this Office Action - even if they had been obvious to combine - one of ordinary skill would not have

arrived at applicants' claimed invention. Reconsideration and withdrawal of the §103 rejection are respectfully requested with respect to claims 1 and 19 and to their respective dependent claims.

Regarding any assertion the Office has made out a *prima facie* case of obviousness, applicants again respectfully refer to the data in this application, especially Example 16. These test data are summarized in paragraph [0125] and show that applicants' invention provided a baseline LDL reduction of 21% over "gold standard," extra virgin olive oil. Reconsideration and withdrawal of the §103 rejection are further believed to be in order for this additional reason.

Applicants have made an earnest endeavor to place this application into condition for allowance, and favorable consideration is respectfully requested.

Respectfully submitted,

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